[BIL

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed collection; 60-day comment request; The Genetic Testing Registry

AGENCY: National Institutes of Health, HHS**.**

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995 to provide opportunity for public comment on proposed data collection projects, the National Institutes of Health (NIH), Office of the Director (OD) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Taunton Paine, Director, Division of Scientific Data Sharing Policy, Office of Science Policy, NIH, 6705 Rockledge Dr., Suite 631, Bethesda, MD 20892, or call non-toll free number (301) 496–9838, or Email your request, including your address to: *SciencePolicy@mail.nih.gov*. Formal requests for additional plans and instruments must be requested in writing.

SUPPLEMENTARY INFORMATION: Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires: written comments and/or suggestions from the public and affected agencies are invited to address one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimizes the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Proposed Collection Title: The Genetic Testing Registry, 0925-0651, Expiration Date 11/30/21-EXTENSION, Office of the Director (OD), National Institutes of Health (NIH).

Need and Use of Information Collection: Clinical laboratory tests are available for more than 18,000 genetic conditions. The Genetic Testing Registry (GTR) provides a centralized, online location for test developers, manufacturers, and researchers to voluntarily submit detailed information about the availability and scientific basis of their genetic tests. The GTR is of value to clinicians by providing information about the accuracy, validity, and usefulness of genetic tests. The GTR also highlights evidence gaps where additional research is needed. The GTR now also has tests for microbes like for SARS-CoV-2 to diagnose COVID-19.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 2837.

Estimated Annualized Burden Hours

Type of Respondent	Form Name	Number of Respondents	Number of Responses	Average Time per Response	Total Annual

			per Respondent	(in hours)	Burden Hour
Laboratory Personnel Using Bulk Submission	Minimal Fields	11	16	18/60	53
	Optional Fields	250	16	17/60	1133
Laboratory Personnel Not Using Bulk Submission	Minimal Fields	84	16	54/60	1210
	Optional Fields	57	16	29/60	441
Total		402	6432		2837

Dated: September 1, 2021.

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National Institutes of Health.

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